DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Tele

m3006n

September 17, 1999

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 54

Kathy Hoeft
Administrator
Ashley Medical Center
612 Center Avenue North
Ashley, North Dakota 58413

Dear Ms. Hoeft:

On September 14, 1999, a representative of the State of North Dakota, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection (ID = 208777004) revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, the following Level 1, Level 2, and Repeat Level 3 findings were documented at your facility:

Level 1 Non-Compliance:

1. Processor QC records were missing three of 9 days of operation (33%) in June 1999. Daily sensitometry is required prior to processing clinical films. This

verifies that the film processor ([redacted] M35 or M35A-M) is operating within control limits.

Level 2 Non-Compliances:

2. Mammograms were processed in the film processor ([redacted] M35 or M35A-M) when it was out-of-limits.

3. Processor QC records were missing for three consecutive days for the film processor ([redacted] M35 or M35A-M).

4. Phantom QC records were missing for three weeks for the mammography unit ([redacted]).

5. There was no designated reviewing interpreting physician for your site.

Repeat Level 3 Non-Compliance:

6. The Repeat Analysis QC for the previous two calendar quarters was not adequate because no evaluation of the data was completed

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http://www.fda.gov/cdrh/mammography/index.html*.

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 x 12.

Sincerely,

Edwin S. Dee
Acting Director
Minneapolis District

TWG/ccl